

### Remarks

This is in response to the Office Action dated June 4, 2007.

Per the above amendment, claim 1 has been amended and new claim 11 added. Claim 11 incorporates the subject matter of allowed claim 10, and the subject matter of the claims it depends from. Accordingly, it is believed that claim 11 should now be formally allowed.

Claims 1, 3-6 and 8-9 have been rejected under 35 U.S.C. 103(a) as being obvious over Arkinstall (US5287852) in view of McCoy (US6848242). Claim 7 has been rejected under 35 U.S.C. 103(a) as being obvious over the Arkinstall/McCoy combination and further in view of Augustine (US5638813).

Per the amendment thereto, claim 1 recites, among other features, the nature of the seal above the opening, which is believed to distinguish from the McCoy secretion collection receptacle. It is important to note that the McCoy receptacle is not a gas seal and there is nothing in McCoy to suggest that it seals against gas flow in either direction. McCoy does have a gas seal but it is provided by the cuff on the end of the tracheostomy tube, not by the receptacle. McCoy's cuff isolates the underside of the receptacle from gas pressure so that the lower side of the retainer is not exposed to the gas pressure in the trachea. Whilst McCoy's receptacle may be suitable for collecting secretions that drip on it from above, there is no suggestion that the receptacle be capable of providing a seal against the flow of gas, which can be at a relatively high pressure.

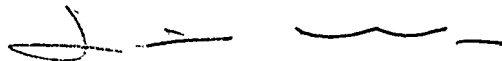
Amended claim 1 now specifies that the gas seal seals against the flow of gas in either direction, and that a lower side of the gas seal is exposed to gas pressure within the trachea. This is now quite different from the arrangement of McCoy where the cuff on the tube isolates the lower side of the receptacle from gas pressure.

Arkinstall describes a tracheal stoma where there is no seal at all in the trachea so that gas is free to flow along the trachea, either out through the mouth and nose or via the tracheal stoma device.

There is, therefore, no teaching in either McCoy or Arkinstall that a gas seal be positioned in the trachea above a tracheostomy opening such that the gas seal is exposed to gas pressure in the trachea and so that the gas seal provides a seal against gas flow along the trachea in either direction. No combination of McCoy and Arkinstall would result in a tracheostomy device with a gas seal arrangement located above the tracheostomy opening and exposed to gas pressure on its lower side and which provides a seal against flow in both directions.

In view of the foregoing, it is respectfully submitted that the instant invention is patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the same to issue at an early date.

Respectfully submitted,



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